



FONDAZIONE REGIONALE
PER LA RICERCA BIOMEDICA

EARLY CAREER AWARD

Guidelines for Reviewers – FULL PROPOSAL

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1. GENERAL INFORMATION

1.1 The context

Fondazione Regionale per la Ricerca Biomedica (FRRB) is a non-for-profit organization governed by public law, established in October 2011 by Regione Lombardia, with the aim of promoting and supporting scientific research in Life Sciences in Lombardy. The Foundation represents one of the main funding agencies that promote progress, research, development and innovation within the health sector among the regional academic and industrial life science players. Its *raison d'être* is to serve as support for implementing the regional health care research policy, in order to place the Lombardy regional system in a leading position in Europe. In addition, the Foundation's mission is to support innovative basic and translational research projects, which have a positive impact on the local healthcare eco-system and on citizens through regional and European competitive calls for proposals.

1.2 The Italian National Health Service NHS (*Sistema Sanitario Nazionale – SSN*)

The Italian National Health Service has been established in 1978. The leading principles of the NHS, funded by public funds, are universal coverage and non-discriminatory access to the health care services. It delivers high-quality health care to all citizens and guarantees vast drug coverage paid by the NHS and all hospital and diagnostics services.

Research projects received in response to this Call should provide evidence of their impact on the NHS. The scientific revision should take into account that the final scope of the funded research will be to integrate new findings and approaches into the NHS and have a clear potential impact on patients.

1.3 Precision Medicine

FRRB, in accordance with Lombardy Region and the Italian Ministry of Health, focuses its activities on the development and implementation of a Precision Medicine approach. "*Precision Medicine*" is defined by the Horizon 2020 Advisory group as the "*medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention*".

To this aim, during scientific evaluation, reviewers should take into account the concept of Personalized Medicine and its potential to move forward to a more personalized approach to prevention, diagnosis and therapy.

1.4 Purpose of this document

This document is a guide to help scientific experts (reviewers) in the revision process of the

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submitted in response to the EARLY CAREER AWARD Call, and to help them understand the environment where the scientific projects will take place and the main needs of the regional territory.

The selection of proposals that will be funded by FRRB is based on a Peer Review process. The aim of this document is to define, in detail, the revision process, the responsibilities of the reviewers appointed, the methodology for revision and the management of any conflict of interest.

Before starting the evaluation process, please carefully read the Call Text and this guide.

For the EARLY CAREER AWARD Call there is a two-stage application process:

- Stage 1: pre-proposal;
- Stage 2: full proposal followed by a Consensus Meeting.

Scientific revisions must be completed by the deadline set in the Contract between the scientific expert and FRRB.

FRRB Scientific Office provides a template for the scientific revision, which will be sent to the scientific experts together with the project/s to be evaluated.

All scientific evaluations must be submitted using the evaluation template. Any other template different from the one provided by FRRB will not be considered acceptable.

2. TECHNICAL INFORMATION

2.1. Score table

In assigning the scores, reviewers should take into account the following table:

Scores	Description
0	Failure: the proposal does not meet the call requirements. Detailed description of project and PI expertise are missing, incomplete and/or not appropriate.
1-2	Very poor: the proposal poorly meets the requirements of the call and present major shortcomings.

3-4	Poor: the proposal poorly meet the requirements of the call.
5-6	Fair: the proposal meets adequately the call requirements, but shows some shortcomings.
7-8	Good: the proposal responds adequately to the requirements of the call and shows only minor weaknesses.
9-10	Excellent: the proposal effectively meets the requirements of the call, and shows no weaknesses.

2.2 Evaluation criteria of the full proposal

Scientific experts have already evaluated pre-proposals submitted in response to this Call, and the best ranked pre-proposals have been invited to submit the full proposal.

Two independent scientific experts will evaluate each full proposal by giving scores and comments. One reviewer could have previously evaluated the corresponding pre-proposal. At the end of the full proposal evaluation, a Consensus Meeting will take place in order to define the final ranking list.

You are invited to perform the evaluation of the full proposal before the Consensus Meeting; in order to perform it, you will receive a full proposal application form, including a budget table, for each project to be evaluated.

The full-proposal application form includes four sections:

1. General information
2. Project description
3. Research team, infrastructures and project management
4. Budget

1. General Information. This section includes general information on the project, such as the title, the research area and the keywords, as well as a brief project summary.
2. Project description. This section includes scientific information about the project.
3. Research team, infrastructures and project management. This section includes information about the research team, the facilities in support of the research that are present at the host institution and the management of the research project.
4. Budget. This section includes the budget justification.

Scientific experts are asked to evaluate full-proposals according to the following table and scores:

EXCELLENCE	Maximum score 20
Clarity and relevance of the objectives illustrated	0-10
Soundness of the hypothesis and of the preliminary data, appropriateness and feasibility of the methodology, ethical aspects included	0-10
IMPACT	Maximum score 20
Advancement beyond state-of-the-art	0-10
Quality of the proposal in terms of: <ul style="list-style-type: none"> - Dissemination and sharing of results to the scientific community - Dissemination of results to the lay public - Description of RRI principles¹ 	0-10
QUALITY AND EFFICIENCY	Maximum score 20
Quality and efficiency of the workplan, adequacy of the resources allocated to each work package in line with the project objectives	0-10
Appropriateness of the technical and management structures of the project	0-10

For each category, reviewers must provide a written comment; for each item, they will have to provide a score, from 0 to 10 (0.5 score points are accepted).

Please note:

- projects are proposed by early career scientists. Many of them might be at the very beginning of their scientific career;
- in this phase the project proposal is as important as the Principal Investigator expertise and background;
- **In order to be admitted to the Consensus Meeting stage, the average of the scores of the two reviewers for each category must be higher than 15 points (threshold).**

2.3. Scoring and weighting

The maximum score of each category is 20, given by the sum of the scores of the individual sub-categories listed in the table.

In order to be admitted to the Consensus Meeting stage, the average of the scores of the two reviewers for each category must be higher than 15 points (threshold).

The maximum score for each pre-proposal is 60, given by the sum of the three categories. At the end of the remote evaluation, a provisional ranking list will be drafted and sent to

¹ Per ulteriori informazioni: https://ec.europa.eu/research/swafs/pdf/rome_declaration_RRI_final_21_November.pdf

the scientific experts involved in the Consensus Meeting (plenary session).

At the end of the plenary session, a final ranking list will be provided and the projects will be funded in order of ranking, up to the available resources.

3. REVIEWERS RESPONSIBILITIES

3.1 Conflict of interest

Any possible conflict of interest has to be excluded before the assignment of the full proposal to the scientific expert.

Should a conflict of interest for any reason arise once the reviewer has seen the pre-proposal, s/he must immediately contact FRRB in order to be replaced.

3.2 The importance of scores and comments

Scores and comments are critical, as they will be taken into account for the initial ranking. Please note: scores and comments will be included in the evaluation report and, therefore, they will be visible to the applicants.

Comments should be of good quality, genuine and substantial. They ideally should be an explanation of strengths and weaknesses of the proposal, according to the evaluation criteria.

Reviewers are obliged to observe the following guidelines:

- Use dispassionate, analytical and unambiguous language.
- Use grammatically correct, complete, clear sentences with no jargon.
- Be constructive.
- Avoid reference to the applicant age, nationality, gender, or personal matters.
- Avoid making reference to scores in the comments.
- Avoid any direct comparison with any other proposals.
- Avoid any reference or comparison with previous assessments.
- Avoid comments that give a description or a summary of the proposal.
- Avoid dismissive statements about the Principal Investigator, the proposed science, or the scientific field concerned.

If the reviewer feels that her/his contribution to the revision process is not appropriate for any reason, s/he will have to contact FRRB in order to be replaced.

IMPORTANT:

You are asked to evaluate projects submitted by early career scientists. Many of them might be at the very beginning of their scientific career. Please be aware that your scores and comments might have an impact on their scientific career!

3.3 Gender issues

Sex and gender differences represent a crucial issue in designing a good research study, but are often overlooked in research design, study implementation and scientific reporting, as well as in general science communication. This leads to a limited generalizability of research results and findings, with limited successful application into clinical practice, especially for women, but also for men.

Moreover, reviewers should consider whether the authors are using the words *sex* or *gender* appropriately, as the term *sex* should be used to classify females and males from a biological point of view.

In particular, the reviewers are asked to check:

- o In human studies, sex of subjects and how it is assigned should be explained: examination of body characteristics, genetic testing or other means. Principal Investigators should rely on the composition of the biological sample.
- o In studies of animals, the term sex should be used to distinguish males and females and authors should rely on the composition of the biological sample in terms of sex of the animals.
- o In cell biology studies, the origin and sex chromosome constitutions of cells or tissue cultures should be stated. If unknown, the reasons should be stated.

The reviewers should also take into account the gender composition of the research team.

For more information, please rely on:

- <https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6>
- https://ec.europa.eu/research/mariecurieactions/gallery/understanding-gender-dimension-msca-projects_en
- <http://genderedinnovations.stanford.edu/methods/sex.html>